510(k) Summary

NOV -- 6 2007

A. Submitted By:
Eagle Heart Imaging, LLC.
8407 Bryant St.
Westminster, CO 80031

Contact: John Koss
Tel: 303-427-2289
Fax: 303-426-8688
E-mail: EagleHeartImaging@comcast.net

Date Prepared: August, 2007

B. Device Trade Name: *Multi-SPECT*
Common Name: Collimator
Device Class: 21CFR 892.1200, Class II
Product Code: 90 KPS

C: Predicate Device(s):
Multiple Pinhole Tomographic Collimator
Engineering Dynamics Corp. (K790499); ADAC Tomography Option (K791055)

This collimator was used as an add on accessory to single headed gamma cameras such as the Picker Dynacamera 4/15, Ohio Sigma 410, or the Siemens LFOV.

Vertex Dual Headed Gamma Camera
ADAC Laboratories (K922080)

The detectors from this camera are used with the new device. Cardiac images from this camera are of typical quality for current SPECT cameras.

AutoSPECT
ADAC Laboratories (K992317)

This software package reconstructs the views acquired by a SPECT system into a 3 dimensional array for data analysis and display.

D: Device Description:
The product consists of two multi-pinhole collimators attached to the two heads of a dual headed gamma camera (eg ADAC (now Philips) Vertex Gamma Camera). The collimators are designed to perform myocardial perfusion studies. Each collimator consists of a 2 x 3 array of pinholes.

Each pinhole is focused on the patient's heart, such that the radioisotope distribution in the heart is seen from 18 different view points. This multiplicity of views allows for tomographic reconstruction of the radioisotope distribution in the heart. Acquisition is done in list-mode, retaining position, energy and patient physiological data. The raw list-mode data is framed and corrected for scatter, then reconstructed into a three dimensional matrix. It can then be analyzed by previously cleared software packages (eg Emory Cardiac Toolbox™ - K040141).

The collimators can be stored in the standard collimator storage device shipped with the camera and exchanged either manually or semi-automatically depending upon the configuration of the original dual headed gamma camera. When changing collimators, the operator needs to activate the pre-programmed exchange motion program. The program prompts the operator to proceed through the steps necessary for the exchange, and provides cautionary warnings to the operator during critical steps as a safety precaution. This is identical to changing the collimators that come standard on dual headed gamma cameras such as the Vertex.

When acquiring data, there is no motion of the camera. The camera heads can only be moved by the operator manually overriding the acquisition program.

E: Intended Use:

The *Multi-SPECT* is intended for use as an accessory to a dual headed nuclear medicine camera such as the ADAC Vertex Dual Headed Nuclear Medicine Camera. It is to be used to perform static, dynamic and/or gated Single Photon Emission Computed Tomography clinical nuclear medicine images of the heart. It is indicated for use to produce images showing the location and distribution of radioisotopes in the human body for interpretation by a physician.

F: Comparison to Predicate Device(s):

The *Multi-SPECT* has the same intended use, target population, and clinical setting as other SPECT cameras including the predicate devices.

It uses the same technology as the predicate device Engineering Dynamics Multiple Pinhole Tomographic Collimator and the ADAC Laboratories Tomography Option, but adds an additional collimator and more pinholes, resulting in more views and an improved sampling geometry of the heart. Due to the additional views, the sensitivity is greater and the resolution of the reconstructed images is both higher and more uniform.

It uses predicate device ADAC Laboratories Vertex Camera for the data acquisition. Replacing the parallel hole collimator on the Vertex Camera with the *Multi-SPECT* pinhole collimator results in images with comparable resolution but with increased sensitivity.

Reconstruction software uses the same underlying mathematical algorithms as the predicate AutoSPECT package, but incorporates the pinhole geometry. The overall result is that the *Multi-SPECT* has improved sensitivity and resolution over the Engineering Dynamics Pinhole Tomographic Collimator and ADAC Laboratories Tomography Option; and has improved sensitivity with equivalent resolution to rotational SPECT cameras such as the ADAC Vertex Camera.

Since motion of the detectors during acquisition is removed, the *Multi-SPECT* raises no new issues of safety or effectiveness; in fact with the motion disabled, safety is increased.

Specification	Engineering Dynamics Multiple Pinhole Tomographic Collimator (Predicate 1) K790499; K791055	ADAC Vertex Gamma Camera (LEHR collimator) (Predicate 2) K922080	This application - *Multi-SPECT*
Number of collimators	1	2	2
Number of pinholes	7	NA (parallel hole)	18
Resolution[1]	10.4 mm	11.0 mm	8.9 mm
Sensitivity[1]	262 kcnts/min/mci	264 kcnts/min/mci	1118 knts/min/mci

[1] Data was acquired at the focal distance for the pinhole collimators (203 mm for the *Multi-SPECT* and 130 mm for the 7 pinhole predicate device). Resolution and sensitivity vary as a function of distance from the collimator face. Data for the predicate Vertex with a LEHR collimator was also collected at 203 mm from the collimator face. Source was a Tc-99m point source.

G: System Performance Test:
Bench testing was performed using NEMA NU 1 phantom(s) or equivalent following NEMA guidelines. A set of three clinical images was also examined.

H: Conclusion:
Eagle Heart Imaging, LLC believes that the *Multi-SPECT* is substantially equivalent to the predicate devices based on intended usage (for cardiac studies), technology comparison and system performance.

Comparison Table of *Multi-SPECT* with Predicate Devices

Specification (NEMA test results)	ADAC Vertex Gamma Camera (LEHR collimator) (Predicate 2) K922080	This application - *Multi-SPECT*
NEMA 2.4 Resolution w/o scatter (source placed 120 mm from detector)	10.0 mm	10.6 mm[1]
NEMA 2.6 Reconstruction resolution w/o scatter	11.0 mm	11.0 mm
NEMA 3.7 Resolution with scatter (source placed 120 mm from detector)	9.2 mm	10.4 mm
NEMA 3.11 Resolution with scatter	15.4 mm	14.3 mm
NEMA 3.12 System Volume Sensitivity (normalized)	1	4.7
Mechanical	Detectors move around patient, needs safety mechanisms	Detectors stationary
Sampling Field of View (radial / longitudinal)[2]	180° / 0°	141° / 40°

Notes:
All measurements made with Tc-99m.

All resolution measurements are average FWHM (averaged in the 3 principal directions).

The Engineering Dynamics predicate (K790499) and ADAC Laboratories Tomography Option (K791055) were not listed in the above table. These predicates are no longer sold and the NEMA tests were not able to be run.

[1] As should be discernable from the above tables, the system resolution for the *Multi-SPECT* collimator is highly dependent on the distance from the pinhole, due to the magnification properties of pinhole imaging. The reconstructed resolution numbers are more indicative of the system capabilities. It should also be noted

that the *Multi-SPECT* resolution and sensitivity numbers can be changed by changing the pinhole diameter. The actual diameter was chosen to approximate the resolution of the predicate device while maintaining a sensitivity advantage.

[2] The top value represents the viewing angle in the radial direction while the bottom value represents viewing angle in the caudal or cephalic directions. The Vertex with LEHR collimator is capable of a full 360° acquisition, but in day-to-day practice the majority of cardiology practices use only 180° acquisition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2007

Eagle Heart Imaging, LLC
% Mr. Morten Simon Christensen
Staff Engineer & FDA Program Office Coordinator
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K073021
Trade/Device Name: Multi-SPECT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: October 25, 2007
Received: October 26, 2007

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073021

Device Name: *Multi-SPECT*

Indications For Use:

The *Multi-SPECT* is intended for use as an accessory to an dual headed nuclear medicine gamma camera (for example - the ADAC Vertex Dual Headed Nuclear Medicine Camera). It is to be used to perform static, dynamic and/or gated Single Photon Emission Computed Tomography clinical nuclear medicine images of the heart. It is indicated for use to produce images showing the location and distribution of radioisotopes in the human body for interpretation by a physician.

Prescription Use ✔ and/or Over-The-Counter Use ____
(Per 21 CFR. 801 Subpart D) (21 CFR 807 Subpart c)

(Please do not write below this line - continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073021